## APPENDIX B

## PENDING CLAIMS

1	1. (As filed) A method of treating a neoplasia in a mammal, said			
2	method comprising administering to said mammal a serum-stable nucleic acid-lipid			
3	particle comprising a nucleic acid portion that is fully encapsulated within the lipid			
4	portion, wherein said administration is by injection at an injection site that is distal to sai			
5	neoplasia in said mammal.			
1	2. (As filed) A method of treating a neoplasia in a mammal in			
2	accordance with claim 1, wherein said nucleic acid comprises an expressible gene.			
1	3. (As filed) A method of treating a neoplasia in a mammal in			
2	accordance with claim 2, wherein said expressible gene encodes a member selected from			
3	the group consisting of therapeutic polypeptides and therapeutic polynucleotides.			
1	4. (As filed) A method of treating a neoplasia in a mammal in			
2	accordance with claim 2, wherein said gene is exogenous.			
1	5. (As filed) A method of treating a neoplasia in a mammal in			
2	accordance with claim 3, wherein said gene is a member selected from the group			
3	consisting of genes encoding suicide enzymes, toxins and ribozymes.			
1	6. (As filed) A method of treating a neoplasia in a mammal in			
2	accordance with claim 2, wherein said gene encodes a member selected from the group			
3	consisting of herpes simplex virus thymidine kinase (HSV-TK), cytosine deaminase,			
4	xanthine-guaninephosphoribosyl transferase, purine nucleoside phosphorylase,			
5	cytochrome P450 2B1 and analogs thereof.			
1	7. (As filed) A method of treating a neoplasia in a mammal in			
2	accordance with claim 2 wherein said gene is homologous.			

1	8. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 2, wherein said gene encodes a member selected from the group		
3	consisting of proto-oncogenes, cytokines, immune stimulatory proteins and anti-		
4	angiogenic proteins.		
1	9. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 2, wherein said gene is a member selected from the group		
3	consisting of IL-2, IL-12, IL-15 and GM-CSF.		
1	10. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 2, wherein a therapeutically effective amount of said gene is		
3	generated at said neoplasia.		
1	11. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein said nucleic acid-lipid particle comprises a		
3	protonatable lipid having a pKa in the range of about 4 to about 11.		
1	12. (As filed) A method of treating a neoplasia in a mammal in		
	accordance with claim 11, wherein said protonatable lipid is a member selected from the		
2			
3	group consisting of DODAC, DODAP, DODMA, DOTAP, DOTMA, DC-Chol, DMRIE,		
4	DSDAC and mixtures thereof.		
1	13. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein said nucleic acid-lipid particle comprises a lipid		
3	conjugate that prevents aggregation during formulation.		
1	14. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 13, wherein said lipid conjugate is a member selected from the		
3	group consisting of PEG-lipids and PAO-lipids.		
J	group consisting of the ripide and the representation		

1	15. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 13, wherein said lipid conjugate is reversibly associated with an		
3	outer lipid monolayer, and wherein said lipid conjugate exchanges out of said outer lipid		
4	monolayer at a rate faster than PEG-CerC20.		
1	16. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein said nucleic acid-lipid particle is substantially devoid		
3	of detergents and organic solvents.		
1	17. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein a therapeutically effective amount of said nucleic acid-		
3	lipid particle accumulates at said neoplasia.		
1	18. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein a therapeutic effect is detected at the site of said		
3	neoplasia.		
1	19. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 17, wherein said therapeutically effective amount comprises		
3	greater than about 0.5% of an administered dose.		
1	20. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein said nucleic acid-lipid particle has a diameter of about		
3	50 nm to about 200 nm.		
1	21. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 20, wherein said nucleic acid-lipid particle has a diameter of about		
3	60 nm to about 130 nm.		
1	22. (As filed) A method of treating a neoplasia in a mammal in		
2	accordance with claim 20, wherein said nucleic acid-lipid particles are of a uniform size.		

1	23.	(As filed) A method of treating a neoplasia in a mammal in	
2	accordance with claim	1, wherein said nucleic acid-lipid particle has a nucleic acid to	
3	lipid ratio of greater th	han about 3 mg nucleic acid to mmole of lipid.	
1	24.	(As filed) A method of treating a neoplasia in a mammal in	
2	accordance with claim	a 23, wherein said particle has a nucleic acid to lipid ratio of greater	
3	than about 14 mg nucleic acid to mmole of lipid.		
1	25.	(As filed) A method of treating a neoplasia in a mammal in	
2	accordance with claim 23, wherein said particle has a nucleic acid to lipid ratio of greater		
3	than about 25 mg nucleic acid to mmole of lipid.		
1	26.	(As filed) A method of treating a neoplasia in a mammal in	
2	accordance with claim 1, wherein said nucleic acid remains at least 90% intact when said		
3	particle containing about 1 µg DNA is treated with about 100 U DNAse 1 in digestion		
4	buffer at 37°C for 30	min.	
1	28.	(As filed) A method of treating a neoplasia in a mammal in	
2	accordance with claim 1, wherein said administering is performed at least once per eight		
3	weeks.		
1	35.	(New) A method of treating a neoplasia in a mammal, in	
2	accordance with claim 5, wherein said gene encodes a suicide enzyme.		
1	36.	(New) A method of treating neoplasia in a mammal in accordance	
2	with claim 35, further comprising administering a prodrug.		
1	37.	(New) A method of treating a neoplasia in a mammal in	
2	accordance with clain	n 36, wherein said prodrug is administered after the serum stable	
3	nucleic acid-lipid particle.		

1	38.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim 36, wherein said prodrug is administered before the serum stable			
3	nucleic acid-lipid particle.			
1	39.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim	9, further comprising administering a chemotherapeutic agent.		
1	40.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim	39, wherein the chemotherapeutic agent is administered after the		
3	serum stable nucleic acid-lipid particle.			
1	41.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim 39, wherein the chemotherapeutic agent is administered before the			
3	serum stable nucleic acid-lipid particle.			
1	42.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim 1, wherein the lipid portion comprises a cationic lipid and a			
3	neutral lipid.			
1	43.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim 42, wherein the cationic lipid is DODAC.			
i	44.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim 42, wherein the neutral lipid is DOPE.			
1	45.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim	42, wherein the lipid portion further comprises a PEG-lipid.		
1	46.	(New) A method of treating a neoplasia in a mammal in		
2	accordance with claim	42, wherein the lipid portion further comprises cholesterol.		